DETAILED ACTION

1. This office action is in response to the reply filed on 6/2/2011.

2. In the reply, the applicant amended claims 25, 30, and 34.

3. Thus, claims 25-34 are pending for examination.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 claims that "drilling debris enters the first opening", where the shaft has "a proximal end with a first opening" and "injecting medicament into the cavity, through the shaft to exit through the second opening" where the shaft has "a distal end with a second opening extending from the distal end through a beveled portion of a cutting tip".

6. Here, the applicant has appeared to claim that hole 38 will have debris enter and fluid will exit through bevel and opening at 36. This appears to be at odds with the applicant's specification. For instance, applicant's specification has bevel and notch (36) perform the cutting and has debris enter'the bevel and notch that form the second opening at the distal end. Proximal first opening 38 appears to remain open for fluid injection. Thus, the claims appear to have confused which opening has debris enter and fluid exiting. Further, it debris entered hole 38, it is likely that the fluid lumen would clog

and fluid would not be able to be delivered to the second distal opening. Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 25-26, 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwan (6135769) in view of Windischman et al (2716983). Kwan discloses a method of injecting medications (Summary; anesthetic solution) into a cavity through a hard tissue having a thickness comprising: a shaft with a proximal first opening (2), a distal end with a second opening extending from the distal ending (3); a lumen between the openings (Fig 1); and using the cutting tip to drill a hole through hard tissue such that debris enters the 2nd opening (Summary; Operation), and injecting a medicament into the cavity, through the shaft to exit through the first opening (Summary; Operation). Also, hub (4).

9. However, Kwan does not expressly disclose an open notch contiguous with the second opening and having a length greater than a diameter of the lumen. Windishman et al teaches that it is known to have an open notch (14) contiguous with the second opening (7) and having a length greater than a diameter of the lumen (Figs 1-5) for the purpose of preventing the cannula from clogging during penetrations and use. It would have been obvious to one having ordinary skill in the art at the time the invention was

made to modify the needle and method of injecting as taught by Kwan with the open notch as taught by Windischman et al for the purpose of preventing the cannula from clogging during penetrations and use.

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kwan in view of Windischman et al. Kwan in view of Windischman et al teaches the drill as above, but does not teach the length of the drill. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the length of the drill be .1-.125 inches because the drill of Kwan in view of Windischman et al is also used for drilling in the mouth. Therefore, it would have been an obvious matter of design choice to modify Kwan in view of Windischman et al to obtain the invention as specified in claim 27.

Response to Arguments

11. Applicant's arguments with respect to claims 25-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 Form.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M. Gilbert/
Examiner, Art Unit 3767

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3763